SEP 2 9 2000

# 510(k) Summary
# Advanced Surgical Concepts
# Omniport Hand Access Device

K002013

## 1. Sponsor

Advanced Surgical Concepts (ASC)
Unit 4, Sunnybank Centre, Bray
County Wicklow
Ireland

Contact Person: Tanya Hoolahan
Telephone: 353 1 2864777

Date Prepared: September 25, 2000

## 2. Device Name

Proprietary Name: Advanced Surgical Concepts Omniport™ Hand Access Device
Common/Usual Name: Laparoscopic/Endoscopic Accessory
Classification Name: Endoscopic Accessory

## 3. Predicate Devices

Medical Creative Technologies Dexterity Pneumosleeve (K962147)
Smith & Nephew Handport (K990414)
MedTech Intromit Hand Access Port (K990663).

## 4. Device Description

The Omniport Hand Access Device allows the surgeon to insert his/her hand into the abdomen during laparoscopic surgical procedures without losing pneumoperitoneum. The Omniport device maintains a gas seal between the operator's arm and the device and between the device and the incision. The Omniport can be left in position for a complete laparoscopic procedure.

## 5. Intended Use

The Omniport Hand Access Device provides abdominal access to the surgeon's hand during laparoscopic surgery while maintaining pneumoperitoneum.

## 6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Omniport Hand Access Device is intended for the same use as the Medical Creative Technologies, Smith & Nephew, and Medtech Hand Access Devices. All of these devices provide abdominal access for the surgeon's hand during laparoscopic procedures while maintaining pneumoperitoneum.

The technological characteristics of the Omniport Hand Access Device are similar to the substantially equivalent devices. All of the devices use flexible access tubes for entry of the surgeon's hand into the abdomen for facilitation of the procedure. All of the devices provide access to the abdominal area while maintaining pneumoperitoneum. The materials used in the Omniport are similar to the materials used in the substantially equivalent devices.

## 7. PERFORMANCE TESTING

Results from the following testing were provided to support the safety and effectiveness of the Omniport Hand Access Device:

- Materials used in the Omniport were subjected to and passed biocompatibility testing according to ISO-10993
- Results from bench testing and animal testing were provided which demonstrate that the Omniport Hand Access Device functions as intended
- Shelf-life and stability test data were provided to support a shelf life of three years for the device

Data from a multi-center clinical trial were provided which demonstrates that the Omniport can be used safely and effectively on patients undergoing various hand-assisted laparoscopic abdominal procedures without adverse effects.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 9 2000

Advanced Surgical Concepts
c/o Ms. Mary McNamara-Cullinane, RAC
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K002013
Trade Name: Advanced Surgical Concepts Omniport Hand Access Device
Regulatory Class: II
Product Code: GCJ
Dated: June 30, 2000
Received: July 3, 2000

Dear Ms. McNamara-Cullinane:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Mark N Melkerson

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002013

Device Name: **Advanced Surgical Concepts Omniport Hand Access Device**

Indications for Use:

The Omniport Hand Access Device provides abdominal access to the surgeon's hand during laparoscopic surgery while maintaining pneumoperitoneum.

(Please Do Not Write Below This Line - Continue On Another Page If Necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhauser

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K002013

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)